AMENDMENTS TO THE DRAWINGS:

Please delete Figure 2c.

REMARKS

Claims 14-17 and 20-22 are pending in the present application. In the present amendment, claims 18 and 19 have been canceled without prejudice. Applicants reserve the right to prosecute the canceled subject matter in one or more related application.

Furthermore, claim 14 has been amended to more particularly describe and claim the invention. Specifically, claim 14 has been amended to recite that the balloon has an outer surface and that a reservoir is disposed about the outer surface of the balloon. The outer surface of the balloon defines one surface of the reservoir and a membrane with pores define another surface of the reservoir. Also, claim 14 has been amended to clarify that the coating is in fluid communication with the reservoir such that the biologically active material in the reservoir can pass through the pores of the membrane and enter the voids. Support for this amendment is found, *inter alia*, on pages 3-5, *e.g.*, paragraphs [0012], [0025] and [0026], as well as Figures 2a and 2b of the specification. Also, claim 17 has been amended to recite that the balloon is connected to an inflation lumen. Support for this amendment is found, *inter alia*, at page 4 of the specification. No new matter is believed to have been introduced by these amendments.

I. OBJECTIONS TO THE DRAWINGS

The Examiner objected to the drawings under 37 C.F.R. 1.83(a). The Examiner stated that since claim 18 recites a perfusion lumen, such feature must be shown in the figures or the feature should be canceled from the claims. Although the Applicants disagree with the Examiner, in order to expedite prosecution, claim 18 has been canceled. Accordingly, the objections to the drawings are obviated.

II. OBJECTIONS TO THE SPECIFICATION

The Examiner objected to the amendments made to the specification, filed on May 6, 2004 under 35 U.S.C. § 132 as introducing new matter. The Examiner alleged that Figure 2c constitutes new subject matter since it is unclear what Applicant originally envisioned as the configuration for the infusion lumen that supplies the sponge coating. Applicants respectfully disagree and submit that the specification is sufficiently descriptive of the depiction of Figure 2c. However, in order to expedite prosecution, the specification is amended so that all references to

Figure 2c have been deleted. Also, Figure 2c has been canceled. Thus, the objections to the specification are believed to have been obviated.

III. CLAIM REJECTIONS UNDER 35 U.S.C. § 103

A. Claims 14, 17, 20-22 Are Patentable Over U.S. Patent No. 5,458,568 to Racchini In View of U.S. Patent No. 5,304,121 to Sahatjian

The Examiner has rejected claims 14, 17-23, 25, 27-33 and 47 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,458,568 to Racchini. ("Racchini ") in view of U.S. Patent No. 5,304,121 to Sahatjian ("Sahatjian"). It should be noted that claims 18-19, 23, 25, 27-33 and 47 have been canceled. Therefore, the rejection of these claims are believed to be moot.

In the Office Action, the Examiner stated that Racchini teaches all of the limitations of the claims except for specifically reciting a non-hydrogel polymer having a plurality of voids. (Office Action at page 3). Specifically, the Examiner stated that Racchini in Figures 2, 3, 5 and 6 teaches a "medical device having a reservoir disposed about a balloon, wherein the reservoir is defined by a membrane having a plurality of pores." (Office Action at page 7). The Examiner further stated that Sahatjian teaches the use of a non-hydrogel polymer having a plurality of voids and that it would have been obvious to one of ordinary skill in the art to modify the sponge coating of Racchini with the non-hydrogel polymer sponge coating of Sahatjian. (Office Action at pages 3-4). Applicant respectfully disagrees with this rejection.

Racchini teaches a catheter having a balloon formed from a porous membrane, *i.e.* the porous membrane forms the outer surface of the balloon (col. 7, lines 7-12; col. 8, lines 33-37). The interior of the balloon can contain drug solutions that can pass through the porous membrane that forms the outer surface of the balloon (col. 8, lines 11-32). Unlike the present invention, Racchini does not teach or suggest a balloon that has an outer surface and additionally, a separate reservoir disposed about the outer surface of the balloon in which one surface of the reservoir is defined by the outer surface of the balloon and another surface of the reservoir is defined by a membrane having pores. Also, Figures 2, 3, 5 and 6 of Racchini only show a balloon formed from a porous membrane. These figures do not disclose or suggest a balloon defined by an outer surface and a reservoir disposed about the outer surface of the balloon as recited in claim 14. Moreover, since Racchini does not teach a reservoir disposed about the balloon, this reference also does not disclose that the reservoir is connected to a reservoir lumen for filling the reservoir with the biologically active material.

Sahatjian does not remedy the deficiencies of Racchini. Sahatjian, like Racchini, also fails to disclose a catheter having a balloon having an outer surface and a separate reservoir disposed about the outer surface of the balloon in which one surface of the reservoir is defined by the outer surface of the balloon and another surface of the reservoir is defined by a membrane having pores. In addition, since Sahatjian does not teach a reservoir disposed about the balloon, this reference also does not disclose that the reservoir is connected to a reservoir lumen for filling the reservoir with the biologically active material. Thus, Racchini and Sahatjian, individually or in combination do not render claims 14, 17 and 20-22 obvious. Therefore, the rejection based on these two references should be withdrawn.

B. Claims 14-17 and 20-22 Are Patentable Over Racchini In View of U.S. Patent Nos. 6,099,562; 6,284,305; 6,620,194 to Ding *et al.*

The Examiner has rejected claims 14-33 and 47 under 35 U.S.C. § 103(a) as being unpatentable over Racchini in view U.S. Patent Nos. 6,099,562; 6,284,305; 6,620,194 to Ding *et al.* (hereinafter the "Ding patents"). It should be noted that claims 18-19, 23-33 and 47 have been canceled. Therefore, the rejection of these claims are believed to be moot. Also, Applicants respectfully submit that claims 14-17 and 20-22 are patentable over these references.

As discussed above, Racchini does not disclose or suggest the present invention. Furthermore, as discussed in the Amendment filed December 15, 2004, the Ding patents cannot be applied as a basis for an obviousness rejection. Pursuant to 35 U.S.C. § 103(c) and M.P.E.P. § 706.02(k), a reference, which qualifies as prior art only under one or more of subsections 35 U.S.C. § 102 (e), (f), and (g), does not qualify as a prior art reference against an application if (1) such application was filed on or after November 29, 1999, and (2) the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

These Ding patents did not issue until after the effective filing date of the present application, April 19, 1998, and thus can only qualify as prior art under 35 U.S.C. § 102(e). The present application was filed on February 7, 2002, which is after November 29, 1999. Pursuant to MPEP 706.02(l)(2), submitted herewith is a statement stating that the present application and the Ding patents were, at the time the claimed invention was made, owned by, or subject to an obligation of assignment to, Schneider (USA), Inc, the predecessor in interest to Boston Scientific Scimed, Inc., the present owner of the Ding patents and the present application. Copies of the relevant assignments were previously filed with the December 15, 2004 amendment. Thus, the Ding patents do not qualify as prior art that can be used in a 35 U.S.C. §

103(a) rejection. Accordingly, withdrawal of this rejection and allowance of the claims are respectfully requested.

C. Claims 15-16 Are Patentable Over Racchini In View of Sahatjian And U.S. Patent No. 5,447,724 to Helmus *et al.*

The Examiner also rejected claims 15-16, 24, 26, 33 and 47 as being unpatentable under 35 U.S.C. §103(a) over Racchini in view of Sahatjian as applied to claims 14, 17-23, 25 and 27-33 and in further view of U.S. Patent No. 5,447,724 to Helmus *et al.* ("Helmus"). It should be noted that claims 24, 26, 33 and 47 have been canceled. Therefore, the rejection of these claims are believed to be moot. Also, for the reasons discussed below, claims 15-16 are patentable over these references.

As discussed above, Racchini and Sahatjian either individually or combination do not teach or suggest the present invention. Moreover, Helmus does not remedy the deficiencies of these two references. Helmus, also does not teach or disclose catheter with a balloon having an outer surface and a separate reservoir disposed about the outer surface of the balloon in which one surface of the reservoir is defined by the outer surface of the balloon and another surface of the reservoir is defined by a membrane having pores. Furthermore, because Helmus does not teach a reservoir disposed about the balloon, Helmus also does not disclose that the reservoir is connected to a reservoir lumen for filling the reservoir with the biologically active material. Thus, Helmus, individually or in combination with Racchini and Sahatjian, do not render claims 15 and 16 obvious. Therefore, this rejection should be withdrawn.

IV. DOUBLE PATENTING REJECTION

Claims 13-33 and 47 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-17 of U.S. Patent No. 6,099,562 to Ding ("the Ding '562 patent") in combination over Racchini. It should be noted that claims 13, 18-19, 23-33 and 47 have been canceled. Therefore, the rejection of these claims are believed to be moot.

Moreover, as noted above, Racchini does not teach or suggest a catheter having a balloon having an outer surface and a separate reservoir that is disposed on the outer surface of a balloon as recited in independent claim 14 and its dependent claims. Also, Racchini does not teach or suggest that the reservoir is connected to a reservoir lumen for filling the reservoir with a biologically active material. The Ding '562 patent does not remedy the deficiencies of Racchini. This patent also does not teach or suggest a catheter having a balloon with an outer surface and a

separate reservoir disposed about the outer surface of the balloon. The Ding '562 patent also does not disclose or suggest that the reservoir is connected to a reservoir lumen for filling the reservoir with a biologically active material. Therefore, the present claims are patentable in view of the Ding '562 patent and Racchini. Thus, withdrawal of this rejection is respectfully requested.

CONCLUSION

Applicants submit that the present claims satisfy all of the criteria for patentability and are in condition for allowance. Withdrawal of the Examiner's rejections and allowance of the claims of the present application are requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same. No fee is believed due for the Amendment. Should any fee be required, please charge such fee to Jones Day Account No. 50-3013.

Respectfully submitted,

Date: November 3, 2005

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